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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,615	06/13/2001	Michael W. Johnson	S63.2-9949	7299

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EXAMINER	
COZART, JERMIE E	
ART UNIT	**PAPER NUMBER**
3726	
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11/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/880,615	JOHNSON, MICHAEL W.	
	Examiner	Art Unit	
	Jermie Cozart	3726	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,27-32 and 36-49* is/are pending in the application.

4a) Of the above claim(s) *31 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,27-30,32,36-40 and 42-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be **material to patentability** as defined in 37 CFR 1.56.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 23, 27-30, 32, 36, 37, 39, 42, 44-46, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan (5,843,172) in view of Solovay (5,769,884) and Stinson (5,980,564).

Regarding **claim 23, 27-30, 44, 45**, Yan discloses a method of manufacturing a stent comprising providing a tube having at least two different longitudinally spaced regions of different predetermined physical characteristics (different pore sizes located along the stent). The tube is formed from metal which is sintered and thereby provided as porous thereby having regions of differing porosity. The stent is cut from the tube after the tube has been formed from sintered metal. A treatment agent (i.e. therapeutic drugs) is disposed on the stent. Note that since the treatment agent has been disposed on the stent and that the stent has different regions of porosity then the treatment agent can be considered as a first and second treatment agent since it is disposed in the different regions of the stent. Yan discloses a stent (12) having been formed according to one embodiment, it is clearly apparent that since Yan discloses forming a stent from a porous tube via laser, it is there safe to surmise that the stent (12) in figure 1 has been formed in the same manner (i.e. laser cutting), wherein stent (12) includes a plurality of serpentine segments extending about the circumference of the stent. As a result of this laser cutting, a plurality of elongate openings are formed whose widths exceed their lengths. *See column 2, lines 7-14 and 39-46; column 3, lines 55-60; column 4, lines 1-11 and 32-65; column 7, lines 30-51; and Figures 1-3 and 6 8 for further clarification.*

Regarding **claims 32, 36, 37, 39**, Yan discloses manufacturing a stent, wherein a tube of sintered metal is provided having different predetermined porosities. The tube is

cut using a laser thereby forming a plurality of openings in the tube which in turn creates a stent (12) as previously rationalized above having multiple serpentine bands. A treatment agent (i.e. therapeutic agent) is disposed on the stent. Note that since the treatment agent has been disposed on the stent and that the stent has different regions of porosity then the treatment agent can be considered as a first and second treatment agent since it is disposed in the different regions of the stent. Some of the openings are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment. The openings which are bounded by at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment include a first side wall and a second side wall extending between and connecting the first and second serpentine segments. The first and second serpentine segments have different physical characteristics (i.e. different porosity). *See column 2, lines 7-14 and 39-46; column 3, lines 55-60; column 4, lines 1-11 and 32-65; column 7, lines 30-51; and Figures 1-3 and 6 8 for further clarification.*

Yan, however, does not disclose the following: the tube having at least two different longitudinally spaced regions of different predetermined porosities and each region having substantially the same porosity about its circumference, the longitudinally spaced regions being longitudinally adjacent to one another, wherein the at least two regions having porosities between 20% and 80% of the volume of the sintered metal; a first portion of the tube being characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube, being characterized by a second porosity different from the first porosity; the at least two regions have porosities

between 40% and 60% of the volume of the sintered metal; or forming multiple serpentine bands such that a first band has a different porosity than a second band.

Solovay discloses a stent covering (30) which is formed into a tube around the stent wherein the tube has at least two different longitudinally spaced regions (12, 13) of different predetermined porosities (see Fig. 6) and each region having substantially the same porosity about its circumference, the longitudinally spaced regions being longitudinally adjacent one another, wherein a first portion (12) of the tube is characterized by a first porosity and second portion (13) of the tube, longitudinally spaced from the first portion of the tube is characterized by a second porosity different from the first porosity. Solovay allows the proper amount of therapeutic agents to be delivered to the treatment site. *See column 3, line 41 – column 6, line 55, and Figures 2, 6, 6A, and 6D for further clarification.*

Stinson discloses the porosity of a region of a stent being between 20% and 80% of the volume of the stent, wherein the porosity is between 40% and 60% of the volume of the stent. *See column 8, lines 4-10 for further clarification.*

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the tube of Yan with at least two different longitudinally spaced regions of different predetermined porosities wherein each region has substantially the same porosity about its circumference, and wherein a first portion of the tube is characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube, is characterized by a second porosity different from the first porosity and to provide the tube of Yan with regions having porosities

between 20% and 80% of the volume of the of stent, more specifically between 40% and 60% of the volume of the stent, in light of the respective teachings of Solovay and Stinson, in order to effectively deliver the desired amounts of therapeutic agents to a particular treatment site within the human body and to provide an effective bioabsorbable stent.

5. Claims 38, 40, 43, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan/Solovay/Stinson as applied to claims 23, 32, and 47 above, and further in view of Richter (5,807,404).

Yan/Solovay/Stinson as modified above discloses all of the claimed subject matter except for the following: a first portion of the tube being made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube being made from a second metal different from the first metal; the first and second side walls being non-parallel to the longitudinal axis of the stent; or at least some of the openings being bounded at a proximal end by a first serpentine segment made of a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal.

Richter discloses a stent (1) having at least two longitudinally spaced regions (8, 9) and (8`,9`) of different predetermined physical characteristics. A first portion (8, 9) of the tube is made from a first metal and a second portion (8',9') of the tube, longitudinally spaced from the first portion is made from a second metal different from the first metal. Richter discloses a plurality of serpentine bands or segments (Fig. 11) extending about the circumference of the stent, and at least some of the openings being bounded at a

proximal end by a first serpentine segment and at a distal end by a second serpentine segment. The first and the second side walls (Fig. 11) are non-parallel to the longitudinal axis of the stent. The first and second serpentine segments having different physical characteristics. Richter discloses at least some of the openings being bounded at a proximal end by a first serpentine segment made a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal. *See column 1, lines 36-54; column 1, line 66 – column 2, line 2; column 4, lines 32 – 40; column 6, lines 5-7, lines 42 – 51, and lines 57-60; column 7, line 63 – column 8, line 22; and Figures 1, 2, and 7-11 for further clarification.*

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the tube of Yan/Solovay/Stinson with a first portion of the tube being made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube being made from a second metal different from the first metal such that the first and second side walls are non-parallel to the longitudinal axis of the stent; and to provide at least some of the openings being bounded at a proximal end by a first serpentine segment made of a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal, in light of the teachings of Richter, in order to provide more flexibility at the ends to allow the stent to accommodate the curvature of a vessel in which the stent is implanted.

Response to Arguments

6. Applicant's arguments with respect to claims 23, 27-32, and 36-49 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jermie Cozart whose telephone number is 571-272-4528. The examiner can normally be reached on Monday-Thursday, 7:30 am - 6:00 pm.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Bryant can be reached on 571-272-4526. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JERMIE E. COZART
PRIMARY EXAMINER

November 8, 2007